1	Student's t test. Dichotomous data are subjected to
_	CHi square of Fisher's exact test, as is appropriate.
2	A power analysis was done to determine the number
3	A power analysis was denie

of patients in each test group in order to show predicted differences. Power analysis applied to an ANOVA using a power of 0.80 with  $\alpha=0.05$ , coupled with prior studies of mean ALT levels and their variances, estimated a need for 21 to 52 patients in each test group to show a mean ALT difference of 15 IU/L. As 3 to 5% of patients are expected to drop out, and factoring in treatment of the control group after six months, 40 patients per group was arrived at.

13 We Claim

hepatitis C virus, comprising administering to said mammal an anti-viral effective amount of at least one interferon, concurrently or sequentially with administering said thymosin or thymosin fragment.

- 2. A method of Claim 1, wherein said interferon is selected from the group consisting of  $\alpha$ -,  $\beta$  and  $\gamma$ -interferons.
- 3. A method of Claim 2, wherein said  $\alpha$ -interferon is interferon  $\alpha$ -2b.
- 4. A method of Claim 1, wherein the step of administering said interferon comprises administering interferon produced by recombinant DNA technology.

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	5. A method of Claim 1, wherein said mammal is a
· !	human, said interferon is an $\alpha$ -interferon, and the
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1	about one million and about three million units of said
5	interferon per administration.
6	6. The method of Claim 1, wherein said mammal is
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- human, said thymosin is thymosin  $\alpha-1$ , and said dose is about 1500 to about 1700  $\mu$ g of said thymosin  $\alpha-1$ .
- A composition comprising a pharmaceutical dosage unit of a pharmaceutically acceptable carrier containing an immune\system-potentiating amount of at least one member selected from the group consisting of thymosin and immune system-potentiating fragments of thymosin in combination with an anti-viral effective amount of at least one interferon, said pharmaceutical dosage unit being capable of promoting in vivo inactivation of hepatitis C virus when administered to mammals infected with said virus.
- A composition of Claim 7, wherein said thymosin is selected from the group consisting of 20 Thymosin Fraction Five and Thymosin  $\alpha-1$ . 21
  - 9. A composition of Claim 7, wherein said interferon is selected from the group consisting of  $\alpha$ -,  $\beta$ -, and  $\gamma$ -interferons.
- 10.\A composition of Claim 9, wherein said  $\alpha$ -25 interferon is interferon  $\alpha$ -2b. 26

A composition of Claim 10, wherein said

interferon is recombinant interferon. The composition of Claim\_7, wherein said

- 3 thymosin is Thymosin Fraction Five, the immune system-4
- potentiating amount is a human immune system-5
- potentiating amount, and said pharmaceutical dosage 6
- unit is from about 900 to about 1200  $mg/m^2$  body surface 7
- area of said human. 8
- the composition of Claim 7, wherein said interferon is an αinterferon and said amount is between 10 about 1 million and about 3 million units of said 11 interferon.
- The composition of Claim 7, wherein said 13 thymosin is Thymosin  $\alpha$ -1, said immune system-14 potentiating amount is a human immune system-15 potentiating amount, and said pharmaceutical dosage 16 unit is from about 900 to about 1200  $\mu$ g/m² body surface 17 area of said human.
  - The composition of Claim 7, wherein said thymosin is Thymosin  $\alpha$ -1, and said pharmaceutical dosage unit contains about 1500 to about 1700  $\mu g$  of Thymosin  $\alpha-1$ .
    - 16. An anti-hepatitis C formulation comprising an immune sytem-potentiating amount of at least one thymosin or an immune system-potentiating thymosin fragment in combination with an anti-viral effective

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amount of at least one interferon in a pharmaceutically acceptable carrier, for use in the treatment of a 2 mammal infected with hepatitis C virus. 3 The formulation of claim 16, wherein said 17. 4 thymosin is selected from the group consisting of 5 Thymosin Fraction Five and Thymosin lpha-1. 6 18. The formulation of Claim 16, wherein said **7**.7 interferon in selected from the group consisting of  $\alpha$ -, 8  $\beta$ -, and  $\gamma$ -interferons. 9 The formulation of Claim 18, wherein said  $\alpha$ -10 interferon is interferon  $\alpha$ -2B. 11 The formulation of Claim 19, wherein said 20. 12 interferon is recombinant interferon. 13 21. The forumlation of Claim 16, wherein said thymosin is Thymosin Fraction Five, said immune system-15 potentiating amount is a human immune system-16 potentiating amount, and said amount is from about 900 17 to about 1200 mg/m2 body surface area of said human. 18 22. The formulation of Claim 16, wherein said 19 interferon is  $\alpha$ -interferon and wherein said anti-viral 20 effective amount is from about 1 million to about 3 21 million units of said interferon. 22 The formulation of Claim 16, wherein said 23

thymosin is Thymosin  $\alpha-1$ , said immune system-

potentiating amount is a human immune system-

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potentiating amount, and said amount is from about 900 to about 1200  $\mu$ g/m² body surface area of said human.

24. The formulation of Claim 16, wherein said thymosin is Thuymosin  $\alpha$ -1, and wherein said amount is about 1500 to about 1700  $\mu g$  of Thymosin  $\alpha$ -1.

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